REMARKS

Status of the Claims

Claims 1-21 are pending, with claims 4-11 having previously been withdrawn from consideration due to restriction requirement.

Claims 1-3 are rejected.

Claim 1 is currently amended.

Claims 12 through 23 are new.

No new matter has been added.

The Claimed Invention

The field of the present claimed invention relates to a device for use in gastrointestinal procedures. More specifically, for an endoluminal colostomy reversal procedure. *See* Published App., ¶ [0002]. In essence, the device serves as an endoluminal colon stabilizing platform for performing endoluminal surgery. The access device 10, as shown in Fig. 1, includes an elongated access member 12 with a longitudinal bore 16. *Id.*, ¶ [0025]. Access member 12 may include a slot 26 which extends from the distal end to window 24, for facilitating removal of a surgical instrument. *Id.*, ¶ [0026]. The access device 10 has a size and shape that permits it to serve several purposes: it increases "precision for locating and visualizing the zone of safety within the future ostomy site, the tube stabilizes the future anastomosis site, permits precise needle puncture, and protects the opposite luminal wall from inadvertent injury." *See* Published Application, ¶ [0027].

As one example of use in a colostomy reversal procedure, access device 10 is introduced into the stoma opening such that window 24 is arranged to face the rectal stump (denoted "r" in Fig. 6). *Id.* ¶ [0035]. A needle (e.g, needle 30 in Figs. 7 & 8) may be used to puncture the tissue to establish communication between the rectal stump "r" and healthy colon "c." *Id.* ¶ [0036]. Guide wire 32 (Fig. 8) is advanced through needle 30, window 24, longitudinal bore 16 of access device 10 and then exits the body. Access device 10 is then removed from the body with guide wire 32 remaining in place by having guide wire 32 traverse slot 26 of the access device until the two

separate. *Id.* ¶ [0037]. Staple holding component 106 and anvil 108 of circular staple instrument 100 are guided into place by way of guide wire 32, as shown in Fig. 9. Once in place, the stapler is fired to attach rectal stump "r" with the healthy colon "c", and then an opening is cut through the respective tissues to complete the communication between the stump and colon. *Id.* ¶ [0038].

Interview

On September 5, 2008, Applicant's representative conducted a telephone interview with the Examiner. The Applicant proposed claim amendments that added a "blunt" distal end to prevent perforation of the body lumen during use of the access device and that the device be capable of stabilizing a gastrointestinal lumen. The Examiner stated that the blunt distal end limitation may be sufficient to overcome Makower but insufficient to overcome Nash because Nash has a blunted end in the drawings. The Examiner further stated that the gastrointestinal limitations were an "intended use" and insufficient to describe the physical structure of the device. The Examiner stated that specific limitations on the size and shape of the device would be required to distinguish over the prior art, but that a merely increasing the size of the device would likely not be a patentable distinction over the cited prior art vascular access devices.

Rejections under U.S.C. §102(b) and §102(e)

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Makower *et al.* (U.S. Patent No. 5,380,290) and under 35 U.S.C. §102(e) as being anticipated by Nash *et al.* (U.S. Patent No. 6,517,518). These same references were applied by the Examiner in the November 21, 2007 Office Action. In response to that Office Action, Applicant amended the claims to recite that the window of the device was sufficient to pass "colostomy" surgical instrumentation. In the July 8, 2008 Office Action, Examiner asserts that this limitation is merely an intended use and does not set forth an inherent size required of the window or access member.

In claim 1 as currently amended, the window is defined as "adjacent the distal end", the window must define "a radial arc ranging from about 90 degrees to about 180 degrees around the

longitudinal axis" (*see* Published App., ¶ [0026]), the distal end of the device must be "sufficiently blunt to prevent perforation of the gastrointestinal lumen during positioning of the device" and the access member must have a "cross-sectional dimension sufficient to stabilize the gastrointestinal lumen." Neither Makower nor Nash meet all of these limitations.

Makower discloses "an improved vascular access device... to facilitate the passage of catheters through tissue and vascular walls while eliminating the need to thread multiple components over a guidewire." *See* Makower, col. 1, lines 7-12 (emphasis added). Thus, Makower discloses a needle 14 with a sharpened tip, which has a groove (slotted opening) 26 for allowing passage of element 24. *Id.* at col. 6, lines 40-55. Makower has enlarged opening 36 (Fig. 9) for accommodating a guidewire. However the opening of Makower is substantially distant from the distal end of the device (See Fig. 9) and does not define an arc between 90 and 180 degrees, as claimed. Moreover, the Makower device is of insufficient size to stabilize a gastrointestinal lumen and contains a sharpened distal end (to aide puncture of a body lumen) in contrast to the blunted end of the claimed device (to prevent perforation of a gastrointestinal lumen). Thus, Makower does not disclose multiple limitations of the claimed invention invention.

Similarly, Nash discloses an "intravascular revasularization system," that allows the securing of catheter 20 (Fig. 1) into a guide-wire 24 without access to either end of the guide wire. *See* Nash, col. 4, lines 6-15 (emphasis added). In essence, the invention of Nash is to position a guidewire in a blood vessel through use of the device and then permit removal of the device once in position. To this end, catheter 20 has a groove 28 connected between window 34 and the distal end of the catheter that facilitates the separation of the device from the guidewire. Nash also discloses a window 34 which is also for accommodating a guidewire. However, in contrast to the claimed invention, window 34 of Nash is again distant from the distal end of the device and defines a radial arc that is less than 90 degrees – because the purpose of window 34 is to provide an access point for a guidewire inserted into the device from a point outside of the body. Moreover, Nash is an intravascular device and is insufficiently sized to stabilize a gastrointestinal lumen as claimed. In contrast, the window of the present invention is sized and shaped so that laparoscopic surgery may

be performed through the window while the device is in place. For these multiple reasons, Nash does not disclose or suggest the claimed invention.

Simply stated, neither the Makower device nor the Nash device is large enough or properly shaped to accept a laparoscope or endoscope while at the same time allowing insufflation of gas to maintain the patency of the a gastrointestinal lumen while performing anastomosis. For this reason and as specifically detailed above, neither Makower nor Nash anticipate or render the claims obvious.

New Claims 12-23

Applicant has added dependent claims 12 to 19 to further define the claimed invention, and added new claims 20 through 23. Applicant submits that these claims are distinguishable over the prior art and patentable.

CONCLUSION

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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